UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ANGIE CRUZ, I.H., AR'ES KPAKA, and RIYA CHRISTIE, on behalf of themselves and all others similarly situated, Plaintiffs, v. HOWARD ZUCKER, as Commissioner of the Department of Health, Defendant.	14 Civ. 4456 (JSR) ORAL ARGUMENT SCHEDULED FOR SEPTEMBER 25, 2015

MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

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Plaintiffs Angie Cruz, Ar'es Kpaka, and Riya Christie, on behalf of themselves and all others similarly situated (the "Class"), respectfully submit this Memorandum of Law in Opposition to Defendant's Motion for Summary Judgment. For the reasons set forth below, Defendant's motion should be denied.

BACKGROUND

The relevant background facts are contained in Plaintiffs' Opposition to Defendant's Local Rule 56.1 Statement of Material Facts, dated September 11, 2015.[1]

ARGUMENT

Summary judgment should be granted only when the court determines that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Where the parties cross-move for summary judgment, the Court analyzes each motion separately, 'in each case construing the evidence in the light most favorable to the non-moving party.'" Victorinox AG v. B & F Sys., Inc., No. 13-cv-4534 (JSR), 2015 WL 3929673, at *1 (S.D.N.Y. June 22, 2015) (quoting Novella v. Westchester Cnty., 661 F.3d 128, 139 (2d Cir. 2011)). "[T]he burden is upon the moving party to demonstrate that no genuine issue respecting any material fact exists. In considering that, . . . all ambiguities must be resolved and all inferences drawn in favor of the [non-moving] party." Gallo v. Prudential Residential Servs., Ltd. P'ship, 22 F.3d 1219, 1223 (2d Cir. 1994) (citation omitted).

The summary judgment standard is not altered by the fact that Plaintiffs challenge a state regulation. A state agency's interpretation of federal law in promulgating a regulation is not entitled to deference. See Turner v. Perales, 869 F.2d 140, 141 (2d Cir. 1989) (distinguishing state agency review of federal law from Chevron deference); DeLuca v. Hammons, 927 F. Supp.

[1] Citations to "¶" herein will refer to paragraphs in Plaintiffs' Opposition to Defendant's Local Rule 56.1 Statement of Material Facts, dated September 11, 2015.

132, 133 (S.D.N.Y. 1996) (same). Accordingly, 18 N.Y.C.R.R. § 505.2(*l*)'s legality is an "issue of law, subject to *de novo* review." Turner, 869 F.2d at 141; DeLuca, 927 F. Supp. at 133; see also Orthopaedic Hosp. v. Belshe, 103 F.3d 1491, 1495 (9th Cir. 1997).

I. PLAINTIFFS HAVE STANDING.

There are three well-established requirements for standing: 1) injury; 2) "a causal relationship between the injury and the challenged conduct"; and 3) "likelihood that the injury will be redressed by a favorable decision." Ne. Fla. Chapter of Associated Gen. Contractors of Am. v. City of Jacksonville, Fla., 508 U.S. 656, 663-64 (1993) (quotations omitted) [hereinafter Ne. Fla Chapter]. Defendant argues that the first prong, injury, has not been established in three ways: 1) that Plaintiffs lack standing to challenge §505.2(*l*)'s age restrictions; 2) that Plaintiffs fail to show evidence of medical need for the procedures they seek; and 3) that Plaintiffs lack standing to challenge the procedures listed in § 505.2(l)(4)(v) (the "Deemed Cosmetic Procedures") because they have not applied for, and been denied, coverage for those procedures. Defendant's arguments fail.

A. Plaintiffs Have Standing to Challenge the Age Restrictions.

Defendant argues that because the named Plaintiffs are over 21, they have not suffered injury from the age restrictions of § 505.2(*l*). (Def. Br.[2] at 4.) Defendant conflates individual standing with the concept of class standing.

The question of whether a named plaintiff has "class standing," meaning standing to assert claims on behalf of absent class members, does not turn on whether the named plaintiff has standing to pursue those claims in her own right. See NECA-IBEW Health & Welfare Fund v. Goldman Sachs & Co., 693 F.3d 145, 158 (2d Cir. 2012) (named plaintiff had standing, in

[2] Citations to "Def. Br." refer to Defendant's Memorandum of Law in Support of Defendant's Motion for Summary Judgment, dated August 28, 2015.

securities class action, to pursue claims on behalf of purchasers of certificates from offerings where plaintiff was not a purchaser); Tidwell v. Schweiker, 677 F.2d 560, 565 (7th Cir. 1982) (rejecting defendant's argument that standing on behalf of the class was absent if named plaintiff did not have standing himself). Rather, once the named plaintiff establishes individual standing to assert one or more claims, she may then have standing to represent claims of absent class members ("class standing"), even on claims as to which the plaintiff individually lacks standing. NECA, 693 F.3d at 164 (named plaintiff that had individual standing to assert some claims against defendant also had class standing to assert claims on which it had no Article III standing individually). Here, the named plaintiffs each have class standing against Defendant.[3]

As the Second Circuit has stated, "a plaintiff has class standing if he plausibly alleges (1) that he personally has suffered some actual . . . injury as a result of the putatively illegal conduct of the defendant, . . . and (2) that such conduct implicates the same set of concerns as the conduct alleged to have caused injury to other members of the putative class by the same defendants." NECA, 693 F.3d at 162 (quotations omitted). These requirements are indisputably met here. The first prong is met because § 505.2(*l*) excludes coverage for the Deemed Cosmetic Procedures, Cruz v. Zucker, No. 14-cv-4456, 2015 WL 4548102, *13 (S.D.N.Y. July 29, 2015), thus injuring Plaintiffs by facially prohibiting them from getting Medicaid coverage for these procedures. The second prong is also satisfied because Defendant's exclusion of coverage for the Deemed Cosmetic Procedures "implicates the same set of concerns" as the denial of coverage for surgeries and hormone therapy for youth class members—namely, exclusion of coverage for

[3] Because this is a class standing issue, and not an Article III standing issue, it should be decided in the class certification context, not on summary judgment. NECA, 693 F.3d at 158 n.9, 159 (once Article III standing established, "inquiry shift[s] to a class action analysis" regarding ability of named plaintiff to assert claims on behalf of class); Bais Yaakov of Spring Valley v. Houghton Mifflin Harcourt Publishers, Inc., 36 F. Supp. 3d 417, 421 (S.D.N.Y. 2014) (class standing "is an issue to be decided on a motion for class certification").

treatment of GD. See NECA, 693 F.3d at 149, 158 (named plaintiff had class standing to assert securities claims on behalf of holders of securities it did not own because claims implicated same set of concerns); Tidwell, 677 F.2d at 565-66 (named plaintiff had standing to assert claims on behalf of class members who suffered the same harm—"deprivation of Social Security benefits"—but in a different way).

Moreover, Defendant's argument that Plaintiffs cannot pursue claims regarding non-coverage of hormone therapy and surgeries for the youth Class members ignores the history of this litigation. When this lawsuit was commenced, there was a blanket ban on coverage for GD treatment, including for GRS, the Deemed Cosmetic Procedures, and hormone therapy, regardless of age. (¶ 166.) The Court's class certification order defined the class to include all Medicaid-eligible persons with GD whose costs of treatment are not reimbursable by Medicaid pursuant to § 505.2(*l*), regardless of age. (¶ 115.) Defendant stipulated to class certification. (Id.) At that point, the Class "acquired a legal status separate from the interest asserted by" the named plaintiff. Sosna v. Iowa, 419 U.S. 393, 399 (1975). It was only after that point that Defendant amended § 505.2(*l*), and did so in a way that afforded the named plaintiffs coverage of *some* medically necessary treatments for GD, while still barring *all* medically necessary treatments to class members under 18 and all sterilizing surgeries to those under 21. But that does not eliminate the named plaintiffs' class standing to continue to pursue all claims on behalf of all members of the Class. See Sosna, 419 U.S. at 401 ("Although the controversy is no longer alive as to [plaintiff], it remains very much alive for the class of persons she has been certified to represent."); Lynch v. Dawson, 820 F.2d 1014, 1016 (9th Cir. 1987) ("As long as some members of the class of plaintiffs will lose [M]edicaid eligibility as a result of [defendant's] action, standing will be preserved," even if the named plaintiff was not injured by defendant's conduct);

Tidwell, 677 F.2d at 565 (finding class standing to challenge a state agency form where named plaintiff never used the form because "every plaintiff suffered the identical harm—deprivation of Social Security benefits. Only the precise means by which the injury was inflicted were different."); see also Gratz v. Bollinger, 539 U.S. 244, 260-68 (2003) (holding plaintiffs who had already graduated had standing to challenge race-based college admissions policies).

Indeed, in Sosna, for instance, the named plaintiff pursued a class action to strike down Iowa's residency requirement for divorces. During the pendency of the case, however, and after a class was certified, the named plaintiff achieved residency status in Iowa and obtained a divorce in another state. 419 U.S. at 398-99 & n.7. But the Court held that those events did not defeat her class standing because post-class certification, the class had its own "legal status." Id. at 399; see also Lynch, 820 F.2d at 1016 ("the fact of certification will preserve a class's standing even after the named individual representatives have lost the required 'personal stake'") (quotation omitted).

Nevertheless, if the Court were to hold that the named plaintiffs lack standing to challenge the age-based restrictions imposed by § 505.2(*l*), Plaintiffs respectfully request leave to amend to allow other individuals to step into the shoes of the named plaintiffs and represent the interests of the Class in pursuing these claims. At this juncture, at least two individuals stand committed to join this lawsuit and prosecute Plaintiffs' challenge to the age-based restrictions to the fullest: (i) a New York Medicaid recipient under 21 who seeks genital surgery to treat his GD (see Pierce Decl.); and (ii) the mother of a New York Medicaid recipient under 18 who seeks hormone therapy to treat her GD (see Harrison Decl.). Granting leave to amend is particularly preferable here in light of the prejudice that would result to the Class from dismissal based on standing. This lawsuit has been pending for over a year, during which time Class members have

been deprived of access to desperately needed care, the consequences of which are well-known to lead to severe depression, and in some instances, self-harm and suicide. (¶¶ 278, 331, 343.) Furthermore, discovery has already completed in this matter, making it far more efficient to continue this case than have to start anew. And Defendants would not be prejudiced by the addition of new plaintiffs, as Plaintiffs would not require any additional discovery from Defendant, and Defendant has already made substantive arguments for summary judgment on the age restrictions. The interests of justice weigh against dismissal. See Fed. R. Civ. P. 1, 15.

B. Evidence of Medical Need Is No Barrier to Plaintiffs' Standing.

Defendant argues that named plaintiffs Ms. Cruz and Ms. Kpaka have failed to produce medical records showing that they have a medical need for the Deemed Cosmetic Procedures they seek and thus have "failed to establish that they have been harmed." (Def. Br. at 6.) Defendant is in no position to complain about the absence of such proof, however. For one thing, Plaintiffs informed Defendant months ago that they did not intend to produce documents created after the date of the complaint and Defendant neither protested nor moved to compel. Because any medical records of the type Defendant describes would have post-dated the complaint, their absence from Plaintiffs' production is easily explained. Furthermore, although Defendant was free to take the depositions of each of the named plaintiffs and examine them on their medical history, he elected not to. Had he done so, Defendant would have learned the information he baselessly complains of being denied. (See ¶¶ 107-14.) Defendant concedes that Plaintiffs have provided such evidence for Ms. Christie. (Def. Br. at 5 n.3.)

Regardless, Defendant is wrong on the law in any event because proof of medical need is not required to establish standing. When the government erects a barrier to a benefit for a group of individuals, someone within that group who challenges the barrier "need not allege that he would have obtained the benefit but for the barrier in order to establish standing." Ne. Fla

Chapter, 508 U.S. at 666 (plaintiff had standing to challenge ordinance establishing racial and gender quotas for public contracts despite no proof that plaintiff would have actually been awarded a contract); see also Regents of Univ. of California v. Bakke, 438 U.S. 265, 281 n.14 (1978) (plaintiff challenging race-based admissions policy did not need to prove that he would have been admitted in absence of the policy to establish standing). Defendant's standing argument on lack of proof of medical need therefore fails. See Ne. Fla Chapter, 508 U.S. at 666 (proof of ultimate entitlement to sought-after benefit unnecessary to establish standing).

C. Plaintiffs Have Standing to Challenge the Exclusion of Deemed Cosmetic Procedures.

In a similar vein, Defendant argues that Plaintiffs "lack standing for want of ripeness" regarding the Deemed Cosmetic Procedures because "there is no evidence that any of them has been denied prior approval for any of the presumptively cosmetic procedures which they seek." (Def. Br. at 7.) That argument also fails. First, this is the same argument that Defendant made on his motion to dismiss, and just as the Court rejected it then, the Court should reject it again now. It is the law of the case that § 505.2(*l*) bars coverage for the Deemed Cosmetic Procedures. The regulation has not changed since the Court denied Defendant's motion to dismiss, and, as explained below and in Plaintiffs' opposition to Defendant's motion for reconsideration (ECF No. 92), nothing has occurred since that ruling that would warrant revisiting it. Simply put, Plaintiffs were not required to apply for coverage to proceed with this suit. (See infra at II.A.)

Second, Defendant's ripeness argument amounts to nothing more than an effort to impose an exhaustion requirement on Plaintiffs, albeit by a different name. But "exhaustion is not a prerequisite to an action under § 1983," Patsy v. Bd. of Regents of State of Fla., 457 U.S. 496, 500-01 (1982), nor under § 1557 of the Affordable Care Act ("ACA"). Rumble v. Fairview Health Servs., No. 14-cv-2037, 2015 WL 1197415, at *11 (D. Minn. Mar. 16, 2015). Because

all of Plaintiffs' claims are brought under those provisions, there is no exhaustion requirement and Plaintiffs were not obliged to apply for the Deemed Cosmetic Procedures before filing suit.

Third, Defendant's argument also appears to be an attempt to moot Plaintiffs' claims and evade judicial scrutiny of its unlawful acts. That is not permitted. Ne. Fla. Chapter, 508 U.S. at 662 ("a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice.").

Finally, Defendant previously conceded that the submission and disposition of claims for coverage of the Deemed Cosmetic Procedures is irrelevant to a facial challenge to § 505.2(*l*) and should not be heard to take a different position on that same issue now. Specifically, in opposing Plaintiffs' motion to compel documents sufficient to show whether Defendant and managed care organizations were approving or denying requests for coverage of the Deemed Cosmetic Procedures, Defendant argued that Plaintiffs sought documents that were not "relevant to the claims asserted in the Amended Complaint." (Chenitz Decl. ¶ 9 (ECF No. 61).) The Court agreed, holding that the requested information would not be "relevant or necessary to proving [Plaintiffs'] claims." (ECF No. 62). If Defendant's current treatment of coverage claims is irrelevant to Plaintiffs' facial challenge,[4] as Defendant insisted, then Plaintiffs' application for coverage, or lack thereof, cannot be relevant to whether Plaintiffs' claims are "ripe" either.[5]

[4] Defendant notes that Ms. Christie has been approved to receive breast augmentation surgery by her managed care organization. (Def. Br. at 7 n.5.) Recently, Ms. Christie has also received approval for facial feminization, and Ms. Kpaka has been approved for breast augmentation and facial feminization as well. But the issue of whether any named plaintiffs, or Class members, have been approved for coverage of the Deemed Cosmetic Procedures is irrelevant, as explained below. Indeed, Plaintiffs explained in connection with their motion to compel that some managed care organizations have decided to provide coverage for the Deemed Cosmetic Procedures, while others have not. (See Garcia Decl., 8/13/15 (ECF No. 57).) But what some managed care organizations have decided to do does nothing to change the Court's decisions that § 505.2(*l*) does not provide coverage, and that the implementation of § 505.2(*l*) is irrelevant.

[5] Alternatively, if the Court were to decide to depart from its prior ruling that § 505.2(*l*) bars

II. THE COURT SHOULD DENY SUMMARY JUDGMENT ON THE MEDICAID ACT CLAIMS.

The Medicaid Act 1) requires states to provide coverage for medically necessary treatments that fall within certain mandatory categories of services pursuant to the Availability Provision; 2) mandates that services that are provided to some Medicaid recipients may not be denied to other Medicaid recipients pursuant to the Comparability Provision; and 3) requires states to provide coverage for medically necessary treatments for patients under 21, regardless of whether those treatments are covered for people over 21, pursuant to EPSDT. Plaintiffs moved for summary judgment on these claims because the record unequivocally shows that the Deemed Cosmetic Procedures, sterilizing surgeries for people under 21, and surgeries and hormone therapy for people under 18 are all medically necessary to treat GD in certain cases and are made available to Medicaid recipients to treat diagnoses other than GD. It is also undisputed that these treatments are generally accepted by the medical community to be safe, effective, and proven to treat GD. Defendant now argues that the restrictions on these treatments established by §505.2(*l*) "are permissible restrictions on coverage for treatment that is either not medically necessary or not medically accepted." (Def. Br. at 1.) Defendant is wrong and his motion for summary judgment on Plaintiffs' First, Second, and Sixth Claims for Relief (the "Medicaid Act Claims") should be denied because Defendant has misstated the law governing these claims and made factual assertions that are either unsupported, or plainly contradicted, by the record.

A. The Court Should Deny Summary Judgment On Plaintiffs' First Claim For Relief Under the Availability Provision.

Section 1396a(a)(10)(A) of title 42, the "Availability Provision" of the Medicaid Act, mandates that a state "must" "provide for making medical assistance available, including at least

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coverage of the Deemed Cosmetic Procedures, and that Plaintiffs no longer have a valid facial challenge as a result of the June Guidance, Plaintiffs respectfully request that the Court grant Plaintiffs leave to amend their complaint to bring an as-applied challenge.

the care and services listed in paragraphs (1) through (5), (17), (21), and (28) of section 1396d(a) of this title, to all individuals" who meet certain Medicaid eligibility criteria. 42 U.S.C. § 1396a(a)(10)(A) (emphasis added). Defendant's motion should be denied because Defendant misstates the law, the June Guidance does not have the effect that Defendant contends it has, and Defendant is wrong about the medical necessity of treatments for youth with GD.

1. Medicaid Requires Coverage of Mandatory, Medically Necessary Treatments.

Title XIX of the Social Security Act of 1965 establishes the Medicaid program, 42 U.S.C. §§ 1396 *et seq.*, for "the purpose of enabling each State, as far as practicable under the conditions in such State, to furnish . . . medical assistance [to persons] whose income and resources are insufficient to meet the costs of *necessary medical services*." 42 U.S.C. § 1396-1 (emphasis added). Section 1396d(a) in turn lists mandatory and optional categories of coverage. States *must* provide coverage for the mandatory categories, including physician's services and inpatient and outpatient hospital services. See id. §§ 1396a(a)(10)(A), 1396d(a)(1), (2), (5). And states must cover medically necessary treatments that fall within the scope of the mandatory categories. See, e.g., Pinneke v. Preisser, 623 F.2d 546, 549 (8th Cir. 1980) ("basic categories of medical assistance [must] be provided to all categorically needy persons when the assistance is medically necessary."); Moore ex rel. Moore v. Reese, 637 F.3d 1220, 1233 (11th Cir. 2011); Hern v. Beye, 57 F.3d 906, 911 (10th Cir. 1995); Dexter v. Kirschner, 984 F.2d 979, 983 (9th Cir. 1992). Medical necessity is therefore not just a "useful heuristic," as Defendant inaccurately suggests (Def. Br. at 8 n.6), but the lodestar that defines the scope of mandatory coverage.

Misreading the statute, its implementing regulations, and the cases interpreting them, Defendant contends that the states are free to deny coverage for medically necessary treatment even for mandatory categories of coverage. (See Def. Br. at 8-9.) None of the authorities cited

by Defendant in support of that remarkable proposition say any such thing. In Harris v. McRae, 448 U.S. 297 (1980), for example (Def. Br. at 8, 15), the Court faced the question whether states must provide coverage for medically necessary abortions for which federal funding was prohibited by the Hyde Amendment. Harris, 448 U.S. at 307. The Court held that the answer was no, because the Hyde Amendment effected a statutory exclusion of certain abortions from the scope of mandatory coverage, leaving the states free to provide coverage if they so chose. Id. at 309-10. Harris is therefore irrelevant here because (i) it did not deal with the requirement to provide medically necessary coverage for the mandatory categories and (ii) no federal law effects an exclusion of GD-related care from coverage equivalent to the exclusion at issue there.

Roe v. Norton, 522 F.2d 928 (2d Cir. 1975) (Def Br. at 8 n.6) is completely inapposite too. Roe addressed a state statute that prohibited coverage for (in the court's view) non-medically necessary abortions (elective abortions where the mother's health was not at risk). The court merely held that states were not required to cover such non-medically necessary procedures, although they were free to do so at their option. See Roe, 522 F.2d at 933. Here, by contrast, the procedures *are* medically necessary and fall within mandatory service categories, which New York is required to cover. E.g., Hern, 57 F.3d at 911.

2. States Cannot Place Outright Bans on Coverage.

Although a state may place certain limits on coverage, such limits must ensure that the scope of coverage is "sufficient in amount, duration, and scope to reasonably achieve its purpose," and states are not permitted to "arbitrarily deny or reduce the amount, duration, or scope of a required service . . . solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(b), (c). The limits must be "appropriate[,] . . . based on such criteria as medical necessity or on utilization control procedures." Id. § 440.230(d). Utilization control procedures include "'prior authorization processes, or similarly designed processes, to control access,

prevent fraud, or streamline efficiency,' or 'resources to determine the medical necessity of a procedure.'" Davis v. Shah, No. 12-cv-6134, 2013 WL 6451176, at *12 (W.D.N.Y. Dec. 9, 2013), appeal argued, No. 14-543 (2d Cir. Jan. 5, 2015) (quotation omitted). And definitions of medical necessity cannot "remove from the private physician the primary responsibility of determining what treatment should be made available to his patients," but merely establish "that the physician is required to operate within such reasonable limitations as the state may impose." Rush v. Parham, 625 F.2d 1150, 1156 (5th Cir. 1980) (Medicaid "is centered around the judgment of the private physician."); see also Pinneke, 623 F.2d at 549-50 & n.3 (medical necessity "rests with the individual recipient's physician and not with clerical personnel or government officials"). Indeed, Medicaid "create[s] a presumption in favor of the medical judgment of the attending physician in determining the medical necessity of treatment." Weaver v. Reagen, 886 F.2d 194, 200 (8th Cir. 1989).

Here, New York has defined medical necessity as anything "necessary to prevent, diagnose, correct or cure conditions in the person that cause acute suffering, endanger life, result in illness or infirmity, interfere with such person's capacity for normal activity, or threaten some significant handicap," N.Y. Soc. Servs. L. § 365-a(2), as Defendant acknowledges (Def Br. at 8-9 n.6). New York also recognizes the importance of a physician's clinical judgment, mandating that, in the context of prior approval, a practitioner's professional expertise "is entitled to significant weight in reaching a determination and cannot be outweighed solely by the opinions of non-medical personnel or persons not within the same medical profession as the ordering or treating practitioner." 18 N.Y.C.R.R. § 513.6(e).

The Medicaid regime thus distinguishes between reasonable limits on covered treatments and outright bans on medically necessary treatments for particular diagnoses. A state may do the

former, but cannot do the latter. See Pinneke, 623 F.2d at 549 (creation of an "irrebuttable presumption" that procedure "can never be medically necessary" is invalid); Hern, 57 F.3d at 911 (unlawful for state to "categorically den[y] coverage for a specific, medically necessary procedure except in those rare instances when the patient's life is at stake"); White v. Beal, 555 F.2d 1146, 1151 (3d Cir. 1977) ("We find nothing in the federal statute that permits discrimination based upon etiology rather than need for the service.").

3. Summary Judgment Should Be Denied on the Deemed Cosmetic Procedures.

Defendant's entire argument supporting his motion for summary judgment on the Deemed Cosmetic Procedures is that the procedures are covered as a result of the June Guidance, and that the prior approval regime purportedly established thereby is a permissible utilization control measure. (Def. Br. at 10-11, 15.) Both arguments fail.

Even if the standards set forth in the June Guidance were applicable here—they are not—DOH presently has no process in place for determining the medical necessity of the Deemed Cosmetic Procedures that are supposedly subject to prior approval, the process for developing that process is merely in its "infancy," there is no deadline for when that process will be functional, and nobody is tasked with moving that project forward.[6] (¶ 260.) Without a system in place, Defendant cannot possibly call this a permissible utilization control. See Chisholm v. Hood, 133 F. Supp. 2d 894, 901 (E.D. La. 2001) (where availability of required services "is more theoretical than actual," the "system falls woefully short of complying with federal law.").

More fundamentally, the issue here is not whether the June Guidance imposes

[6] Even if the prior approval process described in the June Guidance did exist, the process appears to conflict with DOH's own regulation on prior approval. The June Guidance labels the Deemed Cosmetic Procedures as presumptively cosmetic. To the extent this eliminates the "significant weight" to be given the treating physician and substitutes DOH's judgment for the physician's, this violates 18 N.Y.C.R.R. § 513.6(e) and the principle that the "presumption" should be "in favor of the medical judgment of the attending physician." Weaver, 886 F.2d at 200.

permissible limits on coverage but rather whether § 505.2(*l*) does. Defendant argues that § 505.2(*l*) requires "prior approval of treatments of the kind listed under § 505.2(*l*)(4)(v), which are presumed to be nontherapeutic absent a showing of medical necessity." (Def. Br. at 10.) But this prior approval process is nowhere to be found in § 505.2(*l*), which the Court held "by its plain terms, excludes coverage for the procedures deemed 'cosmetic.'" Cruz, 2015 WL at *13.

The Court's interpretation of the regulation's plain meaning is now the law of the case, which "posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." Arizona v. California, 460 U.S. 605, 618 (1983), decision supplemented, 466 U.S. 144 (1984). This doctrine applies in cases like this where a court has previously determined the meaning of an unambiguous instrument. Frito-Lay, Inc. v. Bachman Co., 704 F. Supp. 432, 438 (S.D.N.Y. 1989) (on summary judgment, court's ruling on earlier motion regarding meaning of statute's plain language was law of the case); State Farm Mut. Auto. Ins. Co. v. Mallela, No. 00-cv-4923 (CPS), 2002 WL 31946762, at *16 (E.D.N.Y. Nov. 21, 2002) (court's ruling on earlier motion interpreting New York State no-fault insurance regulations was law of the case).

Defendant's attempt to re-write § 505.2(*l*) via the June Guidance, fails as a matter of law.[7] Indeed, when a regulation is unambiguous, there is no need to look to any extrinsic evidence whatsoever, including evidence of agency intent. See Christensen v. Harris Cnty., 529 U.S. 576, 588 (2000) (deference to agency interpretation "warranted only when the language of the regulation is ambiguous"); Restrepo v. McElroy, 369 F.3d 627, 639 n.19 (2d Cir. 2004). There are three additional reasons why deference to DOH's "interpretation" of § 505.2(*l*) as

[7] Defendant has filed a motion for reconsideration of the Court's decision on Defendant's motion to dismiss. The reasons stated in Plaintiffs' opposition to that motion showing why no deference should be given to DOH's recent "interpretation" of § 505.2(*l*) are equally applicable here.

reflected in the June Guidance is unwarranted here.

First, a court need not defer to an agency interpretation when the agency's interpretation "conflicts with a prior interpretation." Christopher v. SmithKline Beecham Corp., 132 S. Ct. 2156, 2166 (2012). The Court has already held that the March Guidance made "clear that 'payment will not be made for' the services deemed 'cosmetic,'" just like § 505.2(*l*). Because the June Guidance conflicts with this prior interpretation, no deference is owed.

Second, no deference is warranted when evidence at the time of promulgation demonstrates an intent contrary to the interpretation. See Florez ex rel. Wallace v. Callahan, 156 F.3d 438, 442 (2d Cir. 1998). Here, the evidence from the amendment process, and immediately afterwards, makes clear that DOH's intent matched the plain words of § 505.2(*l*)—that there is no coverage: the Deemed Cosmetic Procedures were referred to as "non-covered" in internal DOH emails (¶ 237); DOH staff expressed concern that an alternative definition of "cosmetic" could result in payment for the procedures (¶¶ 238-39); revisions to the draft regulation proposed by Plaintiffs that would have made clear that the Deemed Cosmetic Procedures were covered were communicated to DOH, but rejected (¶¶ 242-43); DOH's cost estimates for the procedures to be covered by § 505.2(*l*) did not include any estimate of the Deemed Cosmetic Procedures (¶¶ 244, 246); and after the amendment DOH communicated to managed care organizations and others that the Deemed Cosmetic Procedures were not covered (¶¶ 248-53).

Third, no deference is afforded where "there is reason to suspect that the agency's interpretation 'does not reflect the agency's fair and considered judgment on the matter in question,'" but instead is a post-hoc, "convenient litigating position" designed to shield "past agency action against attack." Christopher, 132 S. Ct. at 2166. There is plenty reason for such suspicion here, as all of the contemporaneous documentation makes clear that DOH intended the

Regulation to exclude coverage for the Deemed Cosmetic Procedures, regardless of medical necessity. (¶¶ 237-53.) And it was not until *after* Defendant lost this aspect of his Motion to Dismiss that he sought to issue the new guidance. (See ¶¶ 254-55.)

Moreover, the June Guidance does nothing to change the meaning of § 505.2(*l*) as a matter of New York law. Under the New York State Administrative Procedure Act ("SAPA"), the June Guidance is a mere interpretive document, without the force of law. SAPA § 102(2)(a)(i). Further, because it purports to alter § 505.2(*l*)'s plain terms, it constitutes a new rule under SAPA and Defendant was required to undergo the SAPA rulemaking procedure, including a notice and comment period, before the "guidance" could have any effect. Id. §§ 102(2)(a)(i), 202; Destiny USA Dev., LLC v. New York State Dep't of Envtl. Conservation, 879 N.Y.S.2d 865, 868 (App. Div. 2009) (agencies may not legislate through "guidance"); Yaretsky v. Blum, 456 F. Supp. 653, 656-57 (S.D.N.Y. 1978) (agency "memoranda" that "significantly affect the rights of the public" did not meet exception to SAPA rulemaking requirement). Accordingly, if DOH wishes to change its policy and cover the Deemed Cosmetic Procedures—as it concededly should—it must further amend § 505.2(*l*) before this case may be put to rest.

Finally, even if the June Guidance effected a modification of § 505.2(*l*) to permit coverage of the Deemed Cosmetic Procedures—it does not—this would not moot Plaintiffs' claims because "a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice." Ne. Fla. Chapter, 508 U.S. at 662. This is particularly true where, as here, "repeal of the objectionable language would not preclude [defendant] from reenacting precisely the same provisions" after the litigation concluded. Id. (quotation omitted). Indeed, if the Court were to grant summary judgment to Defendant without ruling on the illegality of the exclusion of the Deemed Cosmetic Procedures,

there would be nothing to stop Defendant from issuing yet another "superseding" guidance that once again restricts coverage. See City of Mesquite v. Aladdin's Castle, Inc., 455 U.S. 283, 289 (1982) (challenge to ordinance not moot where "repeal of objectionable language would not preclude [city] from reenacting precisely the same provision"); Bell v. City of Boise, 709 F.3d 890, 898-901 (9th Cir. 2013) (challenge to ordinance not mooted by police chief's voluntary change in "policy" on enforcement of the ordinance because chief could change policy at any time and there had been no change to the challenged ordinance).

4. Summary Judgment Should Be Denied on the Youth Restrictions.

Defendant argues that DOH has placed "permissible age limitations on hormonal and surgical treatments for minors," as these restrictions are "medically appropriate in light of existing evidence and medical consensus." (Def. Br. at 11, 15.) Because none of Defendant's arguments regarding the youth restrictions has any merit, summary judgment should be denied.

First, as to the age 21 requirement on sterilizing surgeries, Defendant admits his blunder in promulgating this restriction in the first place. (Def. Br. at 14.) Defendant now argues that "judicial intervention is not warranted in light of the ongoing process to amend the age limitation." (Id. at 14-15.) But DOH's designated representative, by whose testimony DOH is bound, testified that there is no such process underway, and no timetable for when the amendment will occur. (¶¶ 76, 320.) Even if Defendant had done anything to address matters since that deposition was taken, because no notice of proposed rulemaking has yet been published in the state register, any such amendment would not become effective for months. (¶ 144.) In any event, Defendant's promise to fix an "error" he never should have made in the first place is no basis to deny Plaintiffs the relief they seek, particularly in circumstances like the present, where the "error" is causing needless harm to needy New Yorkers who are improperly being denied medically necessary care. Indeed, Defendant cites no legal authority (and Plaintiffs

know of none) that would support his bald assertion that—in light of the yet to be implemented plan—"judicial intervention is not warranted." (Def. Br. at 15.)

Second, as to surgeries for people under 18, Defendant asserts that this restriction "is entirely consistent with the prevailing medical consensus." (Def. Br. at 13.) Defendant offers no expert opinion on this issue, instead relying on a selective, and wrong, reading of the SOC. The SOC do recommend that a criterion for *genital* surgery be that the patient have reached the "[a]ge of majority in a given country," but specifically state that chest surgeries may be performed earlier. (¶¶ 324, 355.) Plaintiffs' experts have confirmed that chest surgeries are medically necessary for some people under 18, and have also explained that other surgeries—including genital surgery—are medically necessary in some cases as well. (¶¶ 323, 325-26.) In other words, contrary to Defendant's assertions otherwise, his position is entirely *inconsistent* with prevailing medical consensus.

Finally, as to Defendant's age 18 restriction on hormone therapy, Defendant makes two arguments: 1) New York "has decided to restrict Medicaid coverage for outpatient drugs to prescriptions for medically accepted indications"; and 2) states may "place limitations on coverage for treatments or services that are not medically accepted or are experimental." (Def. Br. at 11-12.) Because both are flawed, this aspect of Defendant's motion must also be denied.

The Medicaid Act permits a state to "exclude or otherwise restrict coverage of a covered outpatient drug if" the prescribed use "is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B). The term "medically accepted indication" is defined as "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act . . . or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section." Id. § 1396r-8(k)(6).

A "covered outpatient drug" in turn "does not include any drug . . . provided as part of, or as incident to and in the same setting as . . . (D) Physicians' services." Id. § 1396r-8(k)(3). The medically accepted indication exclusion therefore does not apply to any drugs provided in the context of a physician visit. 42 U.S.C. § 1396r-8(k)(3)(D). (See also ¶¶ 287-94.) Thus, regardless of whether the use of hormone therapy to treat people with GD under 18 are medically accepted indications, federal law requires that Defendant cover these hormones when provided during a physician visit, which Defendant has concededly not done. (Def. Br. at 11-13.)

Defendant's characterizations of the state of current medical evidence do not support his position either. Defendant argues that there is "scant medical research on the long-term effects of using pubertal suppressants to treat GD in minors." (Def. Br. at 13.) But that ignores that there are serious ethical concerns with conducting randomized control trials for GD and the difficulties inherent in getting large population studies in this context. (¶ 72.) Indeed, it is simply not possible to conduct such research for GD because the patient population is so small to begin with, and it would be unethical to leave someone with the severe distress associated with GD untreated for a sufficient amount of time to get verifiable results. (Id.) This is also irrelevant. The test for whether a treatment can be excluded as experimental or unsafe is not tied to the quality of studies, but rather whether the treatment is "generally accepted by the professional medical community as an effective and proven treatment for the condition for which it is being used. . . . [And] if the service or treatment is not yet generally accepted, is rarely used, novel or relatively unknown, then authoritative evidence must be obtained that it is safe and effective" to require coverage. Rush, 625 F.2d at 1156 n.11; see Miller ex rel Miller v. Whitburn, 10 F.3d 1315, 1320 (7th Cir. 1993) (quoting Rush, 625 F.2d at 1156); Weaver, 886 F.2d at 198-99 (same); McLaughlin ex rel. McLaughlin v. Williams, 801 F. Supp. 633, 638 (S.D.

Fla. 1992) (same). The evidence is clear that hormone therapy to treat people under 18 with GD meets this standard: the treatment is generally accepted by practitioners treating GD to be effective, safe, and proven. (¶¶ 330, 333-43, 359-60.) Whether it should be prescribed for a particular patient is thus a matter best left to practitioners—not politicians and bureaucrats who lack any training on this, let alone expertise—based on a patient's medical need. (¶¶ 270, 356.) Defendant has no evidence to the contrary.[8]

B. The Court Should Deny Summary Judgment On Plaintiffs' Second Claim For Relief Under the Comparability Provision.

Section 1396a(a)(10)(B), the "Comparability Provision," mandates that "medical assistance made available to any [categorically needy] individual . . . (i) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual, and (ii) shall not be less in amount, duration, or scope than the medical assistance made available to [other needy] individuals." 42 U.S.C. § 1396a(a)(10)(B). This provision "precludes states from discriminating against or among the categorically needy," Rodriguez v. City of New York, 197 F.3d 611, 615 (2d Cir. 1999), "applies equally to mandatory and optional medical services" alike, Lankford v. Sherman, 451 F.3d 496, 505 (8th Cir. 2006), and governs "situations where the same benefit is funded for some recipients but not others," Rodriguez, 197 F.3d at 615-16.

Defendant does not dispute that many of the Deemed Cosmetic Procedures are made

[8] Defendant argues that it is "nearly universally accepted" that hormone therapy should not be used to treat GD before a child has entered puberty. (Def. Br. at 13.) But Plaintiffs do not seek coverage of hormone therapy for pre-pubertal patients; the proper course of treatment is to administer pubertal suppressants beginning at Tanner Stage 2, as Defendant concedes. (Def. Br. at 13; ¶¶ 69, 345-46.) Defendant also concedes it is "widely accepted" that cross-sex hormones may be prescribed before age 18. (Def. Br. at 13.) These are all reasons to strike down the age 18 restriction, not uphold it.

available for diagnoses other than GD.[9] As to those, therefore, there is no question but that denying coverage for those same procedures for patients with GD runs afoul of the Comparability Provision. In an effort to salvage this transparently unlawful restriction, however, Defendant suggests that coverage may be available pursuant to the June Guidance, which presumes that coverage will not be available unless the patient obtains prior approval upon a showing of medical need. (Def. Br. at 16.) But this argument must fail for the reasons detailed above. (Supra, II.A.3.) And even if the Deemed Cosmetic Procedures were available for GD on the terms stated in the June Guidance, summary judgment would nevertheless be inappropriate because individuals with GD would still be treated differently than those with other diagnoses, as there is no evidence that DOH considers the procedures to be presumptively cosmetic when used to treat diagnoses other than GD.

With respect to the age restrictions on surgeries, Defendant maintains that they do not violate the Comparability Provision because "DOH applied the same standard that is applied to all coverage determinations." (Def. Br. at 17.) But Defendant provides zero factual support for this assertion, which is reason enough to deny this aspect of the motion. It is also not true: Defendant has already admitted that the age 21 restriction is baseless, and besides, parents can provide consent on behalf of their minor children for other surgeries, but DOH will not allow such consent for the *same surgeries* when used to treat GD. (¶¶ 320, 322.)

Finally, Defendant concedes that pubertal suppressants are available to treat non-GD diagnoses (Def. Br. at 17), and does not dispute that hormones for people under 18 are unavailable to treat non-GD diagnoses. (¶ 351.) Instead, he asserts that New York's alleged "policy" to only cover drugs for medically accepted indications has been "uniformly" applied

[9] To the extent Defendant suggests that tracheal shaving, facial feminization, and body sculpting procedures are not covered for other diagnoses, Defendant is wrong. (Def. Br. at 16; ¶¶ 286-94.)

"with respect to pubertal suppressants" such that the failure to cover those medications for some patient populations, but not others, may be excused. (Def. Br. at 17.) The difficulty here is twofold: Defendant's assertions are (i) unsupported and (ii) wrong. In truth, there is no evidence that there is any such DOH-approved formal "policy,"[10] and if there is, that it has been applied uniformly at all. (¶¶ 364-65.) It is also irrelevant, because the Comparability Provision governs "situations where the same benefit is funded for some recipients but not others." Rodriguez, 197 F.3d at 615-16. If DOH has made hormone therapy available for other people under 18, it must also make it available to the Class members under 18.

C. The Court Should Deny Summary Judgment On Plaintiffs' Sixth Claim For Relief Under EPSDT.

The Early and Periodic Screening, Diagnostic, and Treatment Provision ("EPSDT") requires states to provide "early and periodic screening, diagnostic, and treatment services" to Medicaid recipients under 21. 42 U.S.C. §§ 1396a(a)(43), 1396d(r). States therefore *must* provide, *inter alia*, screening services (at regular intervals, but also whenever medically necessary) and "[s]uch other *necessary* health care, diagnostic services, treatment and other measures described in [42 U.S.C. § 1396d(a)] to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, *whether or not such services are covered under the State plan*." Id. § 1396d(r)(1), (5) (emphasis added). Defendant concedes that EPSDT "requires States to provide all medically necessary care to Medicaid recipients under the age of 21." (Def. Br. at 17.) Indeed "every Circuit which has examined the

[10] After Defendant certified completion of his document production, he produced a copy of the purported "policy," which was not available to DOH personnel who worked on amending § 505.2(*l*). (¶¶ 366-67.) That "policy," however, was stamped with the word "DRAFT" and there is no record evidence that the Court can or should credit on this motion establishing that it was officially approved. Jeffreys v. City of New York, 426 F.3d 549, 555 (2d Cir. 2005) (no need to credit testimony that so improbable that "no reasonable juror would undertake the suspension of disbelief necessary to credit").

scope of the EPSDT program has recognized that states must cover every type of health care or service [medically] necessary for EPSDT corrective or ameliorative purposes that is allowable under § 1396d(a)." S.D. ex rel. Dickson v. Hood, 391 F.3d 581, 590 (5th Cir. 2004).[11]

Defendant nevertheless argues that there is "not adequate evidence or medical consensus to support the use" of hormone therapy or GRS to treat GD in persons under 18. (Def. Br. at 18.) This argument fails for the reasons stated above: 1) Defendant has conceded the medical necessity of these treatments; 2) Plaintiffs' experts have demonstrated the medical necessity of these treatments; and 3) the treatments are widely accepted by the medical community as safe, proven, and effective. (¶¶ 327, 330, 333-43, 350, 359-60.)[12]

III. THE COURT SHOULD DENY SUMMARY JUDGMENT ON PLAINTIFFS' FIFTH CLAIM FOR RELIEF.

Defendant also moves for summary judgment on Plaintiffs' Fifth Claim for Relief, which seeks relief for Defendant's violation of the antidiscrimination provision of the ACA, 42 U.S.C. § 18116. According to Defendant, that claim should be dismissed because "a medical diagnosis of GD" does not constitute "protected class status on the basis of sex," and even if it did, Plaintiffs cannot show discriminatory treatment because all Medicaid recipients are treated alike, whether diagnosed with GD or not. (Def. Br. at 22.) Defendant is wrong on both fronts.

It is clear that sex discrimination includes discrimination against transgender individuals because it subsumes discrimination based on gender identity, gender nonconformance, and gender stereotyping, among other things. See Rumble, 2015 WL at *10, *31 (denying motion to

[11] See also Parents' League for Effective Autism Servs. v. Jones-Kelley, 339 F. App'x 542, 547 (6th Cir. 2009); Collins v. Hamilton, 349 F.3d 371, 376 n.8 (7th Cir. 2003); Pediatric Specialty Care, Inc. v. Ark. Dep't of Human Servs., 293 F.3d 472, 480 (8th Cir. 2002); Katie A., ex rel. Ludin v. Los Angeles Cnty., 481 F.3d 1150, 1154 (9th Cir. 2007); Pittman v. Sec'y, Fla. Dep't of Health & Rehab. Servs., 998 F.2d 887, 889 (11th Cir. 1993).

[12] Tellingly, Defendant does not argue that the medically accepted indication policy applies to EPSDT, as treatments must be covered for people under 21 where medically necessary, even if the state has the option to not cover the treatments for adults. E.g., Katie A, 481 F.3d at 1154.

dismiss sex discrimination claim on basis of transgender status under ACA); Smith v. City of Salem, Ohio, 378 F.3d 566, 572-73 (6th Cir. 2004) (holding that plaintiff with GID stated constitutional and Title VII sex discrimination claims based on allegations of discrimination due to gender nonconformity and appearance); see also Price Waterhouse v. Hopkins, 490 U.S. 228, 250-52 (1989) (Title VII's prohibition against sex discrimination includes discrimination based on gender stereotyping).

Additionally, Defendant's suggestion that the federal government has been silent on this issue (Def. Br. at 19 n.11) is wrong. First, the Office of Civil Rights of the United States Department of Health and Human Services ("HHS") has issued an opinion letter, and various other statements, confirming that the ACA's sex discrimination provision "extends to claims of discrimination based on gender identity or failure to conform to stereotypical notions of masculinity or femininity." (¶¶ 162-64.) The Court may give "considerable deference" to this material in interpreting the meaning of § 1557. Cmty Health Ctr. v. Wilson-Coker, 311 F.3d 132, 138 (2d Cir. 2002). HHS has also published proposed regulations to implement § 1557, which specifically include gender identity within the definition of sex discrimination and prohibit categorical or automatic exclusions from coverage, or limitations on coverage, "for all health services related to gender transition." See Proposed 45 C.F.R. § 92.07(b)(3)-(5). The Court can take account of these proposed regulations as well. Liegl v. Webb, 802 F.2d 623, 627 (2d Cir. 1986). There can thus be no serious doubt that Plaintiffs have protected-class status.

Nor is there any merit to Defendant's assertion that Plaintiffs cannot show that § 505.2(*l*) treats them "differently" than Medicaid recipients diagnosed with other conditions. (Def. Br. at 22.) Defendant's argument in this regard turns entirely on his mistaken belief that this lawsuit challenges the standards in the June Guidance. (Def. Br. at 23-24.) It does not. This action

challenges § 505.2(*l*) (see supra II.A.3), under which there is no question that Plaintiffs are treated "differently," since it imposes coverage bans against the Class members that do not apply to Medicaid recipients with other conditions. (¶¶ 286-94, 314, 328, 351, 361.) In any event, even if the June Guidance were the issue here—it is not—there is no evidence that (i) DOH has established a prior approval process for people with GD, or (ii) that DOH subjects individuals seeking the Deemed Cosmetic Procedures for non-GD diagnoses to a "presumption" of non-coverage, on which the individual bears the burden to overcome.[13]

Indeed, the suggestion that § 505.2(l) and DOH have not singled out transgender individuals for different treatment is absurd. Leaving aside the plain text of § 505.2(*l*), which speaks for itself, the regulation was the culmination of a history of discrimination by DOH against transgender people, beginning in 1998 when DOH placed a categorical ban on treatment despite its own medical director opining that the treatments were safe and effective; continuing through the Medicaid Redesign Team process, when DOH made a "political" decision to maintain its ban on medically necessary treatment, knowing full well that medical evidence commanded that the treatments be covered; and proceeding through the amendment process, with DOH policy staff remarking that GRS is "weird," and referring to transgender care in what DOH has acknowledged were inappropriate and derogatory terms. (¶¶ 117-40, 153-61, 193.)

CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Court deny Defendant's motion for summary judgment, and grant Plaintiffs such other and further relief as the Court deems just and proper.

[13] Moreover, it is open to Plaintiffs to show that even a facially neutral provision has a disparate impact on a protected class and thus violates the ACA. Rumble, 2015 WL at *12. As Defendant has failed to raise any argument with respect to disparate impact in his opening papers, his motion for summary judgment on Plaintiffs' Fifth Claim For Relief should be denied.

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Respectfully submitted,

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